UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,599	01/03/2007	Anke Gasche	1209.003	5413

24955 7590 11/09/2009

ROGITZ & ASSOCIATES
750 B STREET
SUITE 3120
SAN DIEGO, CA 92101

EXAMINER	
CRONIN, ASHLEY L	
ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
11/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,599	GASCHE, ANKE	
	Examiner	Art Unit	
	ASHLEY CRONIN	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) *26-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 September 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/22/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-25, drawn to a kit for inversion of the appendix.

Group II, claim(s) 26-40, drawn to a kit for removal of the appendix.

Group III, claim(s) 41-49, drawn to a method of performing inversion of the appendix.

Group IV, claim(s) 50-60, drawn to a method of performing removal of the appendix.

Group V, claim(s) 61-63, drawn to a method of performing imaging of the appendix.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- Group I has a special technical feature of being a kit for inversion of the appendix
- Group II has a special technical feature of being a kit for removal of the appendix
- Group III has a special technical feature of being a method of performing inversion of the appendix
- Group IV has a special technical feature of being a method of performing removal of the appendix
- Group V has a special technical feature of being a method of performing imaging of the appendix.

3. During a telephone conversation with John Rogitz on October 22, 2009 a provisional election was made without traverse to prosecute the invention of

Group I, claims 1-25. Affirmation of this election must be made by applicant in replying to this Office action. Claims 26-63 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Drawings

4. The drawings have been received on 9/19/2005 and these drawings have been objected to under 37 CFR 1.84 for the following reasons: lines, numbers and letters are not uniformly thick and well defined; and numbers and reference characters are not plain and legible for all figures. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because of the reasons stated above. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Objections

5. Claim 16 is objected to because of the following informalities: line 2 – "wherein said loop is detachable" – this is confusing because it is not claimed what the loop is detachable from. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-3, 5-6, 11, 14-16, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by McClellan et al. (US Pat. No. 6,736,822 B2).

8. Regarding claim 1, McClellan et al. discloses a kit capable of performing an inversion of a vermiform appendix, said kit comprising: a tube 21 (Fig. 11) extending between a proximal end and a distal end 40 (Fig. 11), said tube 21 defining at least one inner channel (Fig. 11), said distal end 40 being adapted to be inserted into a vessel of a patient (in this case a fallopian tube, however, this prior art may be used in other tubular anatomical structures - abstract), an elongated flexible element 44 (Fig. 11) extending between a proximal end and a distal end 43 (Fig. 11) said elongated flexible element 44 being adapted for passing through said inner channel (passes through tube 21; Fig. 11), means 51 (Fig. 11) disposed near said distal end 43 of said elongated flexible element 44 (Fig. 12) for anchoring said distal end of said elongated flexible element 44 to at least one of said interior walls of the tubular anatomical structure (column 8, lines 15-26) when said distal end 43 is disposed within the central lumen of the tubular structure 30 (Fig. 11), such that pulling said elongated flexible element 44 backward provides force for inverting said structure (Figs. 11-13); and means 40, 41 for providing counterforce against said anatomical structure base 31 (Fig. 11) is adapted for being advanced over said elongated flexible element 44 toward said structure base 31

and engaging with said structure base 31 (Figs. 11-13; column 7, line 45 - column 8, line 48).

9. Regarding claims 2-3, 5-6, 11, 14-16, and 25, McClellan et al. further discloses wherein said elongated flexible element 44 is an elongated flexible catheter (column 5, lines 53-56); further comprising a guiding means for guiding said distal end 43 of said elongated flexible element 44 into said central lumen 30 of said tubular structure (column 7, lines 63-67); wherein said means (balloon 51) disposed at said distal end 43 of said elongated flexible element 44 comprises at least one balloon 51 attached to said distal end 43 of said elongated flexible element 44 (column 8, lines 15-26), and wherein said elongated flexible element 44 defines a first inner channel 50 (Fig. 11) in connection with an interior area 52 of at least one balloon 51 for inflating and deflating said at least one balloon 51 (Figs. 11-13; column 8, lines 15-37); wherein said at least one balloon 51 has an outer surface carrying a skid resistant structure 54a, 54b, etc. (barbs - column 8, lines 19-31); wherein said means 40, 41 for providing counterforce comprises an elongated flexible tubular element 40 (Fig. 4) extending between a proximal end and a distal end, said tubular element 40 defining at least one inner channel 45 (Figs. 4-5), said at least one inner channel 45 comprising a first inner channel 45 (capable of receiving a scope - receives catheter 44, and is capable of receiving a scope; Fig. 3); further comprising a ligating means 41 (Figs. 3 and 11-13) being positionable near said tubular structure base 31 for ligating said structure when inverted (Figs. 12-13; column 4, lines 17-36); wherein said ligating means 41 comprises a loop at a distal end 40 (column 4, lines 25-26); wherein said loop 41 is detachable

(column 8, lines 38-48); and wherein said means 40, 41 for providing counterforce against the base 31 of the structure comprises a ring 41 ("loop" – column 4, lines 25-26), wherein said ring 41 is adapted for being advanced over said elongated flexible element 44 toward said base 31 and engaging with said base 31 (Figs. 11-13; column 8, lines 38-48).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over McClellan et al. (US Pat. No. 6,736,822 B2) in view of Trauthen et al. (US Pat. No. 5,263,928).

12. Regarding claims 4 and 10, McClellan et al. discloses all claimed elements ***except for*** wherein said guiding means comprises a wire guide, and wherein said elongated flexible element is a catheter disposed over said wire guide; further comprising a catheter being positionable within an inner channel of a colonoscope for irrigating said central lumen of said appendix.

However, Trauthen et al. teaches a catheter 20 (Fig. 1) and endoscope 26 (Fig. 1) assembly comprising a guiding means consisting of a wire guide 82 (Fig. 1), wherein said wire guide 82 is disposed within said catheter 20 (at distal tip 30; Fig. 1; column 3, lines 24-54), and wherein the catheter 20 is capable of irrigation (via bundle 24 and

irrigation duct 46 – column 4, lines 55-59; Fig. 1), in order to observe, diagnose, and treat body cavities (column 1, lines 7-14).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify McClellan et al.'s device such that said guiding means comprises a wire guide, and wherein said elongated flexible element is a catheter disposed over said wire guide; further comprising a catheter being positionable within an inner channel of a colonoscope for irrigating said central lumen of said appendix, as suggested and taught by Trauthen et al., for the purpose of observing, diagnosing, and treating body cavities.

13. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over McClellan et al. (US Pat. No. 6,736,822 B2) in view of Slepian (US Pat. No. 5,328,471).

14. Regarding claims 7-8, McClellan et al. discloses all claimed elements ***except for*** wherein said elongated flexible element (catheter) defines a second inner channel, said second inner channel having at least one distal opening at the distal end of the elongated element; wherein said at least one balloon comprises a plurality of balloons connect by said first inner channel, and wherein said elongated flexible element defines a second inner channel which includes at least one opening located between any two adjacent balloons.

However, Slepian teaches a balloon catheter assembly 100 (elongated flexible element; Fig. 1b) comprising a first inner channel 152 (Fig. 1b) and a second inner channel 156 (Fig. 1b), a plurality of balloons 150, 151 (Fig. 1b) connected by said first

inner channel 152 and wherein the second inner channel 156 includes at least one opening located between any two adjacent balloons 150, 151 (Fig. 1b), in order to deliver a therapeutic agent through the opening to the procedure site (column 5, lines 39-43).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify McClellan et al.'s device to include a second inner channel, said second inner channel having at least one distal opening at the distal end of the elongated element; wherein said at least one balloon comprises a plurality of balloons connect by said first inner channel, and wherein said elongated flexible element defines a second inner channel which includes at least one opening located between any two adjacent balloons, as suggested and taught by Slepian, for the purpose of delivering a therapeutic agent through the opening to the procedure site.

15. Claims 9, 13, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over McClellan et al. (US Pat. No. 6,736,822 B2) in view of Frassica et al. (US Pat. No. 5,483,951).

16. Regarding claims 9, 13, and 24, McClellan et al. discloses all claimed elements ***except for*** wherein said first inner channel is coated with a lubricious material; and further comprising a colonoscope.

However, Frassica et al. teaches an endoscope assembly (colonoscope - column 1, lines 11-20) comprising a suction channel with a lubricious inner tube forming a lubricious inner lumen (abstract), in order to provide an anti-friction surface for the air and water to pass through (column 9, lines 28-33).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify McClellan et al.'s device such that the first inner channel is coated with a lubricious material, as suggested and taught by Frassica et al., for the purpose of providing an anti-friction surface for the air and water to pass through.

17. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over McClellan et al. (US Pat. No. 6,736,822 B2) in view of Altman et al. (US Pat. No. 4,464,175).

18. Regarding claim 12, McClellan et al. discloses all claimed elements ***except for*** wherein said tubular element further comprises a circular seal disposed within said first inner channel at or near said proximal end of said tubular element, and wherein when a colonoscope is disposed within said first inner channel, said circular seal engages with said colonoscope and seals a region between said colonoscope and said tubular element.

However, Altman et al. teaches a surgical device comprising an outer tube 30 (Fig. 1) wherein the outer tube 30 has a circular diaphragm 25 (Fig. 1) mounted on a cap 22 to provide a seal, wherein the diaphragm has a small opening permitting the passage of an endoscope (column 3, lines 40-48), in order to preserving an air-tight system (column 3, lines 46-48).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify McClellan et al.'s device such that said tubular element further comprises a circular seal disposed within said first inner channel at or near said proximal end of said tubular element, and wherein when a colonoscope is

disposed within said first inner channel, said circular seal engages with said colonoscope and seals a region between said colonoscope and said tubular element, as suggested and taught by Altman et al., for the purpose of preserving an air-tight system.

19. Claims 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over McClellan et al. (US Pat. No. 6,736,822 B2) in view of Griego et al. (US Pub. No. 2002/0095168 A1).

20. Regarding claims 17-21, McClellan et al. discloses all claimed elements ***except for*** further comprising a cutting device for enlarging an orifice of said central lumen of said appendix; wherein said cutting device comprises a sphincterotome; wherein said cutting device comprises a needle knife; wherein said cutting means comprises an elongated wire forming a wire loop at a distal end, said wire being electrically conductive.

However, Griego et al. teaches an endoscopic catheter (Fig. 1) comprising a distally located tissue cutting device wherein the cutting device may be a sphincterotome, a papillotome (wire loop), or a needle knife and the cutting device may operate in response to energy from an rf heating source (paragraph [0016]; electrically conductive – papillotome), in order to cut anatomical tissue that is to be treated endoscopically (paragraph [0019]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify McClellan et al.'s device to include a cutting device for enlarging an orifice of said central lumen of said appendix; wherein said cutting device comprises a sphincterotome; wherein said cutting device comprises a

needle knife; wherein said cutting means comprises an elongated wire forming a wire loop at a distal end, said wire being electrically conductive, as suggested and taught by Griego et al., for the purpose of cutting anatomical tissue that is to be treated endoscopically.

21. Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over McClellan et al. (US Pat. No. 6,736,822 B2) in view of Redha (US Pat. No. 5,282,813).

22. Regarding claims 22-23, McClellan et al. discloses all claimed elements ***except for*** wherein said means disposed at said distal end of said elongated flexible element for anchoring comprises at least one flap disposed at said distal end, said at least one flap being adjustable between a closed and an open position; wherein said elongated element comprises a catheter defining a central lumen and an inner elongated element slidingly received within said central lumen, said inner elongated element defining at least one depression, and wherein said at least one flap comprises a knob extending into said central lumen, said depression engaging with said knob, wherein said at least one flap are adjusted between said closed position and said opened position by operating said inner elongated element.

However, Redha teaches an apparatus delivered and retrieved with a catheter (column 7, lines 37-45) comprising at least one flap 13, 33 (Fig. 2) wherein the flap 13, 33 is adjustable between a closed and opened position (Fig. 1 to Fig. 2) further comprising an inner elongated element 14 (Fig. 1) slidingly received within a central lumen of the device, said inner elongated element 14 defining at least one depression

11 (depression lies where element 24 of structure 11 hits; Fig. 1), and wherein said at least one flap 13, 33 comprises a knob (notch on flaps 13, 33 - Fig. 2) extending into said lumen, said depression 11, 24 engaging with said knob (Fig. 2), wherein said at least one flap 13, 33 are adjusted between said closed and open position by operating said inner elongated element 14 (Fig. 1 to Fig. 2; column 5, line 58 – column 6, line 7), in order to expand the flaps of the assembly during a surgical procedure (column 6, lines 3-7).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify McClellan et al.'s device such that said means disposed at said distal end of said elongated flexible element for anchoring comprises at least one flap disposed at said distal end, said at least one flap being adjustable between a closed and an open position; wherein said elongated element comprises a catheter defining a central lumen and an inner elongated element slidingly received within said central lumen, said inner elongated element defining at least one depression, and wherein said at least one flap comprises a knob extending into said central lumen, said depression engaging with said knob, wherein said at least one flap are adjusted between said closed position and said opened position by operating said inner elongated element, as suggested and taught by Redha, for the purpose of expanding the flaps of the assembly during a surgical procedure.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ASHLEY CRONIN whose telephone number is

(571)270-7899. The examiner can normally be reached on monday-friday, 8am-5pm est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. C./
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
11/05/09